OCT - 5 2000

510(k) SUMMARY

K002751

COM 1: A digital interface for network communication.
Data output every second; SpO_2, and pulse rate
9600 Baud bidirectional

Number of bits per character:	8
Parity	None
Bits	1 start, 1 stop
Handshaking	None
Connector type	9-pin standard D, female
Connector pin functions:	
1	No Connection
2	Receive data – RS-232 ±9 V (±5 Vmin)
3	Transmit data – RS-232 ±9 V (±5 Vmin)
4	No Connection
5	Signal Ground Reference for COM 1 signals
6	No Connection
7	Request to send – Not used
8	Clear to send – Not used
9	No Connection

PRINTER: A connection for optional printer.

Connector pin functions:	
1	No Connection
2	Receive data – Not used
3	Transmit data – RS-232 ±9 V (±5 Vmin)
4	No Connection
5	Signal Ground – Reference for Printer signals
6	No Connection
7	Request to send – Not used
8	Clear to send – RS-232 ±9 V (±5 Vmin)
9	No Connection

Dimensions

Docking Station	
Height	3.5 in (8.9 cm)
Width	10.5 in (26.7 cm)
Depth	7.7 in (19.6 cm)
Weight	4.7 lbs (2.14 kg)
Portable	
Height	8.9 in (22.6 cm)
Width	3.3 in (8.4 cm)
Depth	2.1 in (5.3 cm)
Weight	1.3 lbs (0.59 kg)

[1] The Masimo SET® Radical pulse oximeter with LNOP•Adt sensors has been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70-100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[2] The Masimo SET® Radical Pulse Oximeter with SatShare™ with LNOP-Adt sensors has been validated for motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies while performing rubbing and tapping motions at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70 - 100% SpO_2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[3] The Masimo SET® Radical Pulse Oximeter with SatShare™ with LNOP-Neo and Neo Pt sensors has been validated for neonatal motion accuracy in human blood studies on neonates while moving the neonate's foot at 2 to 4 Hz at an

amplitude of 1 to 2 cm against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

4 The Masimo SET® Radical Pulse Oximeter with SatShare™ has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater than 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

Environmental Testing

Applicable environmetal testing per the Reviewers Guidance for Premarket Submissions - November 1993, i.e. electrical, mechanical and environmental were performed and all tests passed.

Biocompatibility Testing

All patient contact materials were tested as Surface Devices with skin contact for prolonged contact duration (>24 hr to 30 days) as defined ISO-10993-1: 1992 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests. All patient contacting material **passed.**

Nonclinical tests performed that support a determination of substantial equivalence.

The Masimo SET® Radical Pulse Oximeter with SatShare™ and accessories was subjected to bench testing using a simulator that determined the performance accuracy of the instruments against the simulator under the range of saturation and pulse rates that both devices specify.

The results of the bench testing showed that the Masimo SET® Radical Pulse Oximeter with SatShare™ and accessories returned the same saturation accuracy values within ± 2 digits and pulse rate values within ± 3 digits when compared to the simulators used.

Clinical tests performed that support a determination of substantial equivalence.

Clinical studies were performed using the Masimo SET® Radical Pulse Oximeter with SatShare™ on healthy adult volunteer subjects during no motion and motion conditions who were subjected to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

Clinical studies were performed using the Masimo SET® Radical Pulse Oximeter with SatShare™ on neonates during no motion and motion conditions and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

Clinical studies were performed using the Masimo SET® Radical Pulse Oximeter with SatShare™ on healthy adult volunteer subjects who were subjected to low perfusion conditions and to a progressive induced hypoxia and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

Clinical studies were performed using the Masimo SET® Radical Pulse Oximeter with SatShare™ on neonates with low perfusion conditions and measuring the arterial hemoglobin saturation value with the instruments against the arterial hemoglobin oxygen determined from arterial blood samples with a CO-Oximeter.

Clinical studies were conducted following regulations under Title 21 of the Code of Federal Regulations (21CFR), Part 812 - Investigational Device Exemptions, Part 50 - Protection of Human Subjects and Part 56 - Institutional Review Boards.

The results from the clinical studies show that the Masimo SET® Radical Pulse Oximeter with SatShare™ saturation accuracy values for adults and pediatrics within ± 2 digits during no motion conditions and ± 3 digits during motion conditions when compared to the CO-Oximeter and the pulse rate accuracy values within ± 3 digits during no motion conditions and ± 5 digits during motion conditions when compared to the ECG.

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The results from the clinical studies also show that the Masimo SET® Radical Pulse Oximeter with SatShare™ saturation accuracy values for neonates to be within ± 3 digits during both motion and no motion conditions when compared to the CO-Oximeter and the pulse rate accuracy values to be within ± 3 digits during no motion and ± 5 digits during motion conditions when compared to the ECG.

Conclusions

The results of the **environmetal testing** demonstrated that the Masimo SET® Radical Pulse Oximeter with SatShare™ and accessories **met** the requirements of Reviewers Guidance for Premarket Submissions - November 1993.

The results of the **biocompatibility testing** demonstrates the all patient contacting material **met** the requirements of ISO-10993-1: 1992 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests for Surface Devices with skin contact for prolonged contact duration (>24 hr to 30 days).

The results of the **bench testing** demonstrates that the Masimo SET® Radical Pulse Oximeter with SatShare™ **meets** its performance requirements.

The results of the **clinical testing** demonstrates that the Masimo SET® Radical Pulse Oximeter with SatShare™ and accessories **meet** its performance requirements during no motion and motion conditions and low perfusion conditions.

The **non-clinical and clinical testing** performed demonstrates that the Masimo SET® Radical Pulse Oximeter with SatShare™ and accessories is safe, effective.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 5 2000

Mr. James J. Cronin
Masimo Corporation
2852 Kelvin Avenue
Irvine, CA 92614-5826

Re: K002751
Masimo SET® Radical Pulse Oximeter
Models number Radical, LNOP® -Adt, LNOP® -Pdt, LNOP® -Neo, LNOP® -Neo Pt, LNOP® -DCI, PC04, PC08 and PC12, and SatShare Cables
Regulatory Class: II (two)
Product Code: 74 DQA
Dated: September 1, 2000
Received: September 5, 2000

Dear Mr. Cronin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act

for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K002751

Device Name: Masimo SET® Radical Pulse Oximeter with SatShare™ and the LNOP® Series of Sensors and Cables

Indications For Use:

The Masimo SET® Radical Pulse Oximeter with SatShare™ and accessories are indicated for the continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor). The Masimo SET® Radical Pulse Oximeter with SatShare™ and accessories are indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, for patients who are well or poorly perfused in hospitals, hospital-type facilities, mobile, and home environments. In addition the Masimo SET® Radical Pulse Oximeter with SatShare™ and accessories is indicated to provide the continuous noninvasive monitoring data obtained from the Masimo SET® Radical Pulse Oximeter with SatShare™ of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) to multi-parameter devices for display on those devices.

The Masimo LNOP® Series of Sensors are indicated for the following:

A single use oximetry sensor intended for adults and pediatrics greater than 30 kg
A single use oximetry sensor intended for pediatrics and small adults greater than 10 kg and less than 50 kg
A single use oximetry sensor intended for neonates with good skin integrity less than 10 kg
A single use oximetry sensor intended for neonates with poor skin integrity less than 1 kg
A reusable oximetry sensor intended for adults and pediatrics greater than 30 kg
A reusable oximetry sensor intended for pediatrics and small adults greater than 10 kg and less than 50 kg

The Masimo PC Series of Patient Cables are indicated for use with the Masimo LNOP® Series of Sensors and the Masimo SET® Radical Pulse Oximeter with SatShare™.

The following are additional SatShare cables indicated for connection to the following multi-parameter monitors:
Critikon - Dinamap monitors

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002751

Prescription Use ✓ **or** **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)